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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,878	12/19/2001	Mark E. Salvati	LD0297 CIP	6979

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EXAMINER

SMALL, ANDREA D SOUZA

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 07/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/024,878	SALVATI ET AL.	
<b>Examiner</b>	<b>Art Unit</b>		
Andrea D Small	1626		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) 1-4 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some.\* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### ***I. Preliminary Matters:***

- (a) Applicants claim of priority to 09/885,381 and provisional application to 60/233,519 is acknowledged.

### ***II. Applicants Response and Amendment:***

- (a) Applicants response to the restriction requirement filed 4/15/2003 is acknowledged.
- (b) Applicants amendment filed 4/15/2003 is acknowledged.

Claims 3 and 4 have been newly added. No new matter has been added.

Claims 1-4 are pending.

### ***III. Restriction/Election:***

Upon reconsideration of the restriction outlined in office action of 3/17/2003, the Examiner has noted the fact that some of the compounds under the genus of claims 1 and 2 had not been included in any group and that a further restriction is necessary based on the reactants employed, notably the enzyme or microorganism. Thus, the restriction of office action 3/17/2003 has been withdrawn and a new restriction appears below.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1 in part, drawn to method of preparing compound of formula (XVI)  
wherein A1 is C and A2 is C and Z is N, classified in class 548, subclass 449.
- II. Claim 1 in part, drawn to method of preparing compound of formula (XVI),  
wherein A1 is C and A2 is C and Z is O/S, classified in class 548, subclass 451.
- III. Claim 1 in part, drawn to method of preparing compound of formula (XVI),  
wherein A1 is C and A2 is N and Z is O/S, classified in class 546, subclass 80+.

- IV. Claim 1 in part, drawn to method of preparing compound of formula (XVI),  
wherein A1 is N and A2 is C and Z is O/S, classified in class 546, subclass 80+.
- V. Claim 1 in part, drawn to method of preparing compound of formula (XVI),  
wherein A1 is N and A2 is N and Z is O/S, classified in class 544, subclass 346.
- VI. Claim 1 in part, drawn to method of preparing compound of formula (XVI),  
wherein A1 is C and A2 is N and Z is N, classified in class 544, subclass 348.
- VII. Claim 1 in part, drawn to method of preparing compound of formula (XVI),  
wherein A1 is C and A2 is C and Z is N, classified in class 548, subclass 400+.
- VIII. Claim 1 in part, drawn to method of preparing compound of formula (XVI),  
wherein A1 is N and A2 is N and Z is N, classified in class 548, subclass 300+.
- IX. Claim 1 in part, drawn to method of preparing compound of formula (XVIII)  
wherein A1 is C and A2 is C and Z is N, classified in class 548, subclass 449.
- X. Claim 1 in part, drawn to method of preparing compound of formula (XVIII),  
wherein A1 is C and A2 is C and Z is O/S, classified in class 548, subclass 451.
- XI. Claim 1 in part, drawn to method of preparing compound of formula (XVIII),  
wherein A1 is C and A2 is N and Z is O/S, classified in class 546, subclass 80+.
- XII. Claim 1 in part, drawn to method of preparing compound of formula (XVIII),  
wherein A1 is N and A2 is C and Z is O/S, classified in class 546, subclass 80+.
- XIII. Claim 1 in part, drawn to method of preparing compound of formula (XVIII),  
wherein A1 is N and A2 is N and Z is O/S, classified in class 548, subclass 300+.
- XIV. Claim 1 in part, drawn to method of preparing compound of formula (XVIII),  
wherein A1 is C and A2 is N and Z is N, classified in class 546, subclass 80+.

XV. Claim 1 in part, drawn to method of preparing compound of formula (XVIII),  
wherein A1 is C and A2 is C and Z is N, classified in class 548, subclass 400+.

XVI. Claim 1 in part, drawn to method of preparing compound of formula (XVIII),  
wherein A1 is N and A2 is N and Z is N, classified in class 548, subclass 300+.

Inventions of groups I-XVI are patentably distinct from one another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, are not shown as capable of use together and the compounds produced in each inventive group have different effects based on the atoms substituted within or on the ring. For example, the group XVI would be more polar than the group IX by virtue of the former group containing more nitrogen atoms than the latter group, thus having very distinct effects within the body. Additionally, the compounds of formula XVI are distinct from the compounds of formula XVIII in that the compounds of formula XVIII have a di-hydroxy moiety whereas the compounds of formula XVI has a mono-hydroxy moiety, making the latter molecule have a different effect than the former, i.e., the latter is less polar than the former. Further, all these groups are so distinct from one another that a reference that would anticipate but one of the groups would not even render the other obvious. Each group requires a separate database search for which separate search consideration and strategies would have to be employed. Examining all of the above groups in one application would impose a serious burden on the office.

Additionally, claim 1 and claim 2 are generic to a plurality of disclosed patentably distinct species of enzymes and microorganisms that may be employed in the process of

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preparing compound of formula XVI or XVIII, see for example, the microorganism employed in example 458, classified in class 435, subclass 183, versus the microorganism employed in example 459, classified in 435, subclass 253.5. These species are distinct in that they belong to a separate genus and species, which have different processes by which they catalyze a hydroxylation reaction and have acquired a separate status in the art. Searching each species of microorganism would impose a serious burden on the office because each microbe would require a separate search and separate search strategy; strategies, which are not co-extensive. Therefore, along with an election of one of the aforementioned groups, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of microorganism or enzyme, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Upon the election of a single disclosed species of microorganism or enzyme (e.g. Example, page number), the inventive group elected would be limited to the preparation of the compound in that group by employing the particular species of microorganism or enzyme elected. The remainder of the group which employs species of microorganism or enzyme not within the species of microbe or enzyme elected will be withdrawn from consideration as being drawn to non-elected inventions and may then be the subject of divisional applications. 37 CFR 1.142(b).

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Because these inventions are distinct for the reasons given above and the search required for one group is not required for any of the others, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***IV. Contact Information:***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrea D. Small, whose telephone number is (703) 305-0811. The examiner can normally be reached on Monday-Thursday from 8:30 AM - 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

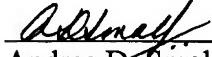
When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [Joseph.McKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy

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July 2, 2003

  
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